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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/016,737 | 01/30/1998 | GERALD P. MURPHY | 8511-007 | 7366 |

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| EXAMINER | |
|---|---|
| DAVIS, MINH TAM B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/016,737 | MURPHY ET AL. | |
| | Examiner | Art Unit | |
| | MINH-TAM DAVIS | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *23-37* is/are pending in the application.

4a) Of the above claim(s) *25,27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26 and 28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 23-24, 26, 28-37 are examined in the instant application.

The following are the remaining rejections.

## REJECTION UNDER 35 USC 102(e)

Claims 23-24, 31-36 remain rejected under 35 USC 102(e) as being anticipated by Cohen et al, for reasons already of record in paper of 08/20/03.

Applicant amends the claims to recite a composition comprising an isolated cell population having human dendritic cells, wherein said cell population has been cultured in the presence of granulocyte-macrophage colony stimulating factor (GM-CSF) and interleukin 4 (IL-4), and exposed in vitro to a soluble prostate antigen.

Applicant argues that Cohen teaches that certain undefined combinations of cytokines have been used to amplify (or partially substitute the calcium ionophore for) the activation/conversion of monocytes to activated dendritic cell-like phenotype, and that this teaching does not anticipate the present invention as no specific combination is cited.

Applicant asserts that the term activation/conversion as used by Cohen refers to mature dendritic cells state at the conclusion of their process and that these activated cells cannot take up and process antigen.

Applicant asserts that Cohen has compared various cytokines to be inferior to the use of calcium ionophore in converting monocytes to activated dendritic cell-like phenotype.

Applicant's arguments have been considered but are found not to be persuasive for the following reasons:

It is noted that there is no limitation in the claims that the cytokines consist of only GM-CSF and IL-4.

Thus composition taught by Cohen et al seems to be the same as the claimed composition, i.e. monocytes that have been exposed to a combination of cytokines comprising GM-CSF, IL-2, IL-4 and IL-12, and prostate cancer cell lysates, wherein exposure to a combination of cytokines would convert monocytes to immature dendritic cells, that could present soluble antigen, as taught by Sallusto et al (abstract and p.1111, first column, first paragraph), to activate specificT cells.

Concerning Applicant's assertion that Cohen has compared various cytokines to be inferior to the use of calcium ionophore in converting monocytes to activated dendritic cell-like phenotype, it is noted that the composition taught by Cohen seems to be the same as the claimed composition, *supra*.

**REJECTION UNDER 35 USC 103**

**1.** Claims 23-24, 31-36 remain rejected under 35 USC 103 as being obvious over Cohen et al, in view of Sallusto et al, and Inaba et al for reasons already of record in paper of 08/20/03.

Applicant asserts that the disclosure of certain combination of cytokines by Cohen et al for activation of monocytes does not teach any combination of cytokines as set forth by the Examiner.

Applicant asserts that the Examiner has yet to set forth where in Cohen et al, or any other references this cell population is taught to take up and process a soluble antigen. Applicant asserts that the activated/converted cells of Cohen cannot take up and process antigen.

Applicant asserts that there is nothing to suggest the combination of Cohen with either Sallusto or Inaba. Applicant asserts that even should the teaching be combined at most it might suggest the addition of an antigen such as tetanus toxoid subsequent to activation/conversion of the monocytes, and as the cells would be unable to process the antigen to activate any T cells.

Applicant's arguments have been considered but are found not to be persuasive for the following reasons:

It is noted that the specific monocytes composition taught by Cohen et al, which is cited in this rejection is not related to monocytes exposed to calcium ionophore.

It is noted that there is no limitation in the claims that the cytokines consist of only GM-CSF and IL-4.

Thus composition taught by Cohen et al, i.e. monocytes exposed to a combination of cytokines that includes GM-CSF, IL-2, IL-4 and IL-12, and prostate cancer cell lysates seems to be the same as the claimed composition, supra.

Further one would have expected that exposure of monocytes or blood mononuclear cells to a combination of cytokines, such as GM-CSF and IL-4 would convert them to immature dendritic cells, that could efficiently present soluble antigen to activate specific T cells, as clearly taught by Sallusto et al (abstract and p.1111, first column, first paragraph).

The motivation to combine Cohen et al with Sallusto et al is that Sallusto et al teach more in details how to activate monocytes using cytokines, and that exposure of dendritic cells produced by exposure to cytokines as taught Cohen et al, or Sallusto et al, to a cancer cell, such as prostate cancer cell lysates taught by Cohen et al would have potential use for treating prostate cancer, because dendritic cells could efficiently present soluble antigen to activate specific T cells, as clearly taught by Sallusto et al, and could reduce the size of prostate tumor, as taught by Cohen et al (Example 2).

Moreover, in view of the teaching of Inaba et al one would have expected that that it is the properties of dendritic cells taught by Cohen et al, and Sallusto et al to activate CD4+ and/or CD8+ T cells.

**2.** Claim 26 remains rejected under 35 USC 103 as being obvious over Cohen et al, in view of Sallusto et al, and further in view of Lutz et al for reasons already of record in paper of 08/20/03.

Applicant asserts that Cohen et al and Sallusto et al do not teach or suggest the dendritic cells of the present invention, and that Lutz et al adds nothing to render obvious the immortalized dendritic cells of the present invention.

Applicant's arguments in paper of have been considered but are found not to be persuasive for the following reasons:

The composition of dendritic cells taught by Cohen et al, and Sallusto et al seem to be the same as the claimed composition, *supra*.

Further, Lutz et al render the claimed immortalized dendritic cells obvious, because Lutz et al teach how to make immortalized dendritic cells to overcome the problem of being unable to maintain dendritic cells in vitro for long periods of time.

**3.** Claim 28-29 remain rejected under 35 USC 103 as being obvious over Cohen et al, in view of Sallusto et al, and further in view of Taylor et al for reasons already of record in paper of 08/20/03.

Applicant asserts that Cohen et al and Sallusto et al do not teach or suggest the dendritic cells of the present invention, and that Taylor et al adds nothing to render obvious the preserved dendritic cells of the present invention.

Applicant's arguments in paper of have been considered but are found not to be persuasive for the following reasons:

The composition of dendritic cells taught by Cohen et al, and Sallusto et al seem to be the same as the claimed composition, *supra*.

Further, Taylor et al render the claimed cryopreserved dendritic cells obvious, because Taylor et al teach how to cryopreserve dendritic cells for use in immunological procedures.

**4.** Claim 30 remain rejected under 35 USC 103 as being obvious over Cohen et al, in view of Sallusto et al, and further in view of Taylor et al and Lutz et al, for reasons already of record in paper of 08/20/03.

Applicant asserts that Cohen et al and Sallusto et al do not teach or suggest the dendritic cells of the present invention, and that there is no motivation to combine the cited references.

Applicant's arguments in paper of have been considered but are found not to be persuasive for the following reasons:

The composition of dendritic cells taught by Cohen et al, and Sallusto et al seem to be the same as the claimed composition, *supra.*

The motivation to combine the teaching of Cohen et al and Sallusto et al with Taylor et al and Lutz et al is for preserving the dendritic cells taught by Cohen et al and Sallusto et all, for use in immunological procedure, as taught by Taylor et al, and for immortalizing dendritic cells to overcome the problem of being unable to maintain dendritic cells in vitro for long periods of time, as taught by Lutz et al

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CHRISTINA CHAN can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

June 05, 2004